PhRMA

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By Messenger

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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Request for Comments on First Amendment Issues
67 Fed. Reg. 34942 (May 16, 2002)
67 Fed. Reg. 45742 (July 10, 2002)
Docket No. 02N-0209

Dear Sir or Madam:

Enclosed are comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) on the above-referenced request for comments on First Amendment issues. Also attached to these comments is a previously submitted "Position Paper on Multiple Trademarks" (April 16, 2002).

Respectfully submitted,

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cc: Catherine Lorraine, Office of Policy,
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02N-0209

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Comments of the
Pharmaceutical Research and Manufacturers of America
PhRMA
In Response to the Food and Drug Administration's Request for
Comments on First Amendment Issues[1]
Docket No. 02N-0209
September 13, 2002

INTRODUCTION

When the Food and Drug Administration (FDA) restricts the speech of pharmaceutical manufacturers and other regulated entities, the restrictions are subject to scrutiny under the First Amendment to the United States Constitution. Recent decisions of the Supreme Court and the lower federal courts make clear that FDA cannot categorically justify such restrictions on the grounds that the restrictions are merely incidental to its regulation of conduct or automatically authorized by its public health mandate. To be sure, FDA may have legitimate interests in restricting speech in certain circumstances. And speech that is false, misleading, or proposes an otherwise unlawful activity is not protected. However, in order to justify limitations on truthful, non-misleading speech about lawful products and activities, the case must be made that both the ends served and the means employed are legitimate and appropriately circumscribed.

Many FDA regulations and policies have not been scrutinized through this First Amendment lens. FDA has a constitutional obligation to ensure that it acts in accordance with the First Amendment, and the agency's request for comments on these issues is a welcome step toward meeting that obligation.

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[1] 67 Fed. Reg. 34942 (May 16, 2002).

PhRMA commends the agency for the proactive and participatory approach it has taken by seeking a public dialogue on these important topics.

PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies invested more than $30 billion in 2001 alone in discovering and developing new medicines. These companies are the source of nearly all new drugs that are discovered and marketed throughout the world.

PhRMA's members disseminate scientific and medical information to enable better patient care and appropriate product usage and disease management. Among other things, PhRMA companies market and promote their products, report on new research findings, engage in scientific exchange with researchers, investigators, and health care professionals, and distribute educational materials to health care providers, health care payors, and patients. PhRMA's members recognize their responsibility to provide truthful, non-misleading information in connection with these activities. At the same time, PhRMA and its members have a fundamental interest in ensuring that their free speech rights are safeguarded, and that the FDA exercises its regulatory authority consistent with the First Amendment.

To these ends, PhRMA believes that FDA should reconsider several aspects of existing and proposed agency policies in light of the prevailing First Amendment case law. These comments address six specific topics:

1. **The dissemination of enduring materials** and support for continuing medical education regarding new/unapproved uses (see p. 12);
2. **Direct-to-consumer advertising** (p. 25);
3. **Use of trademarks and tradenames** (p. 30);
4. **Press releases** (p. 34);
5. **Professional meeting booths** (p. 39); and
6. **Other specific FDA regulations requiring reconsideration** (p. 40).

In relation to the particular questions enumerated in FDA's request for comments,[2] PhRMA's comments touch on Questions 1 (regulation of speech about drugs), 2 (direct-to-consumer advertising), 7 (speech on off-label uses), 8 (public health interests served by FDA speech-related regulations and alternative approaches), and 9 (FDA regulations, policies, etc. that should be revised). Before these specific topics are addressed, however, it is important to make clear the general considerations that govern evaluation of any FDA action that limits constitutionally protected speech.

General Considerations

1. Commercial vs. Non-Commercial Speech

A threshold issue in considering the application of the First Amendment to the regulation of speech in the food and drug arena is whether the speech being restricted is "commercial speech" and therefore subject to intermediate scrutiny, or non-commercial speech and therefore subject to strict scrutiny. Distinguishing between commercial and non-commercial speech can be a difficult exercise, and the cases offer limited guidance. *See Cincinnati v.*

[2] 67 Fed. Reg. at 34943-44.

Discovery Network, Inc., 507 U.S. 410, 419 (1993) ("This very case illustrates the difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category.").

At its core, commercial speech is "speech which does 'no more than propose a commercial transaction.'" *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66 (1983) (quoting *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)). The mere fact that speech is made by a commercial entity does not automatically make it "commercial speech," even if the speaker may have underlying commercial motivations. *Bolger*, 463 U.S. at 67. As the Supreme Court has made clear, the value of speech does not depend on the identity or motive of the speaker.[3] Accordingly, "[i]f commercial speech is to be distinguished [from non-commercial speech], it 'must be distinguished *by its content*.'" *Bates v. State Bar of Arizona*, 433 U.S. 350, 363 (1977) (quoting *Virginia Bd.*, 425 U.S. at 761) (emphasis in *Bates*). Similarly, speech is not necessarily commercial just because it refers to a specific product. *Bolger*, 463 U.S. at 66. On the other hand, speech may be commercial even though it contains a discussion of an important non-commercial societal issue, and a speaker cannot ensure stricter scrutiny by intertwining speech on such public issues with commercial speech. *Bd. of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 475 (1989).

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[3] *See also Pacific Gas & Elec. Co. v. Public Utilities Comm'n*, 475 U.S. 1, 8 (1986) (plurality opinion); *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 777 (1978).

In the pharmaceutical field, there is a spectrum of speech from the clearly commercial to the clearly non-commercial, as well as a great deal in between. Much of the speech by pharmaceutical companies is, of course, commercial. For example, communications such as advertisements and promotional detail pieces that focus on specific products and expressly encourage the purchase or use of the products discussed are generally commercial. Such speech is "linked inextricably to commercial activity." *Friedman v. Rogers*, 440 U.S. 1, 10 n.9 (1979).

In contrast, when researchers affiliated with a company publish study findings in a medical or scientific journal, the publication should not be considered commercial. Other examples of at least presumptively non-commercial speech include medical and scientific information provided in response to unsolicited requests for the information, the exchange of scientific data at scientific meetings, and non-promotional press releases announcing research findings. These and other particular communications are discussed in the sections that follow. As the discussion indicates, various factors may bear on the inquiry of whether speech is commercial or non-commercial, including, for example, whether the information is being provided proactively or reactively, whether the communication is made in a scientific or promotional forum, whether the information has been independently reviewed, and whether the communication is linked to other communications that are more or less commercial in nature.

Some difficult lines may need to be drawn to distinguish between commercial and non-commercial speech. Nevertheless, this threshold issue must be considered when FDA regulates speech, particularly in areas where companies are disseminating scientific and medical information and not promoting a product.

2. Commercial Speech

Where the subject of agency action is commercial speech, any limitation on the speech must satisfy, at a minimum, the well-known test set forth in *Central Hudson Gas & Electric Corp v. Public Service Commission*, 447 U.S. 557 (1980). The First Amendment protects commercial speech because the speech "assists consumers and furthers the societal interest in the fullest possible dissemination of information." *Id.* at 561-62. As the Supreme Court stated in the landmark case of *Virginia Board of Pharmacy*:

> So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

Virginia Bd. of Pharmacy, 425 U.S. at 765.

Under *Central Hudson*, the initial inquiry is whether the speech at issue proposes a lawful transaction and is not misleading. *Central Hudson*, 447 U.S. at 563. Regulations that effectively ban truthful, nonmisleading commercial speech about a lawful product "hinder consumer choice [and] impede debate over central issues of public policy" and, therefore, "rarely survive constitutional review." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503, 504 (1996). On

the other hand, speech that is either false or misleading, or proposes an unlawful transaction, is generally not protected because it does not serve a public purpose. *Central Hudson*, 447 U.S. at 563 ("there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity"). As the Supreme Court has stated, the government rightfully may ensure "that the stream of commercial information flow[s] cleanly as well as freely." *Virginia Bd.*, 425 U.S. at 772.

If the agency seeks to restrict speech on the grounds that it is misleading, the case law makes clear that "FDA may not restrict speech based [simply] on its perception that the speech could, may, or might mislead." *Washington Legal Found. v. Henney*, 56 F. Supp.2d 81, 85 (D.D.C. 1999). Rather, FDA must put forth concrete proof that the restricted speech is actually or inherently misleading. *Ibanez v. Florida Dept. of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994) ("we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden"). *See also Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) (the government's "burden is not satisfied by mere speculation or conjecture").

If speech concerns a lawful activity, and the agency cannot make a record establishing that the speech is in fact misleading, then the agency must satisfy the three remaining prongs of the *Central Hudson* inquiry in order to justify a restriction on the speech. The restriction must (1) promote a substantial governmental interest; (2) directly advance that interest; and (3) be no more extensive than necessary to achieve the asserted government interest. *Central*

Hudson, 447 U.S. at 566. Because the government generally has an undeniable interest in protecting the health and safety of its citizens, among other things, *see Thompson v. Western States Med. Ctr.*, 122 S. Ct. 1497, 1505 (2002), the constitutionality of FDA action (in the case of non-misleading speech) typically turns, first, on whether the action directly advances the asserted government interest, and, second, on whether the government's legitimate interests could be served in a less restrictive way.

To demonstrate that a limitation on speech directly advances a government interest, the government "bears the burden of showing not merely that its [action] will advance its interest, but also that it will do so to a material degree." *44 Liquormart*, 517 U.S. at 505 (internal quotation and citation omitted). The government must prove that "the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71.

To satisfy the final element of *Central Hudson*, agency action that abridges speech must not be "more extensive than necessary to serve" the government's legitimate interests. *Western States*, 122 S. Ct. at 1506 (internal quotation omitted). A restriction is not appropriately tailored if "there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech." *Discovery Network*, 507 U.S. at 417 n.13. "If the government can achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Western States*, 122 S. Ct. at 1499.

A series of instructive rules emerge from the prevailing cases that provide guidance on the application of the *Central Hudson* test.

- First, the constitutionality of a regulation on commercial speech does not depend on the value of the speech, which is left for the speaker and the audience to judge. *Edenfield*, 507 U.S. at 767 ("the speaker and the audience, not the government, assess the value of the information presented"). Accordingly, FDA cannot justify a restriction based on the concern that people will make bad decisions with truthful and non-misleading information. *Western States*, 122 S. Ct. at 1507 ("We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.").[4]

- Second, the greater power to prevent an activity or take some other more draconian regulatory action does not include the lesser power to regulate speech or restrict the communication of truthful and non-misleading information. *Greater New Orleans Broadcasting Ass'n v. United States*, 527 U.S. 173, 193 (1999) ("the power to prohibit or to regulate particular conduct does not necessarily include the power to prohibit or regulate speech about that conduct"). That is, the FDA may not restrict a sponsor's right to commercial speech merely because

[4] *See also 44 Liquormart*, 517 U.S. at 503 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.").

regulation of the sponsor is within the agency's regulatory power. *Washington Legal Found. v. Friedman*, 13 F. Supp.2d 51, 60 (D.D.C. 1998). The Supreme Court clearly has rejected the proposition that, because the government possesses power in one area, it is permitted to restrict speech in that area. *44 Liquormart, Inc.*, 517 U.S. at 512 ("speech restrictions cannot be treated as simply another means that the government may use to achieve its ends"). Rather, if commercial speech is involved, a government agency must satisfy all parts of the *Central Hudson* test.

- Third, a regulatory scheme that purports to advance a government interest through a restriction on speech, but that makes exceptions that permit the same or equivalent speech by other speakers or in other contexts, does not pass constitutional muster. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488-89 (1995) (regulation suffers from "overall irrationality" when the government attempts to prohibit speech in one outlet that it permits in others); *see also Greater New Orleans Broadcasting*, 527 U.S. at 194 ("decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment"). No scheme with such an "overall irrationality" directly advances a substantial government interest, and thus the scheme fails to meet the third prong of the *Central Hudson* test.

- Fourth, if there is an alternate way to meet the asserted government interest that avoids or reduces the restriction on speech, that alternative must be used. As the Supreme Court explained in the recent *Western States* decision: "If the First Amendment means anything, it means that regulating speech must be a last – not a first – resort." 122 S. Ct. at 1507.

- Fifth, it is preferred to require disclosures and/or disclaimers rather than the outright suppression of speech. *Bates*, 433 U.S. at 375-76 ("the preferred remedy is more disclosure, rather than less"). The D.C. Circuit confronted this precise issue recently in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). In that case, the court struck down FDA's refusal to authorize certain dietary supplement health claims, holding that "when government chooses a policy of suppression over disclosure – at least where there is no showing that disclosure would not suffice to cure misleadingness – government disregards a 'far less restrictive' means." *Id.* at 658. The constitutional preference for disclosures and disclaimers flows directly from the rule underscored in *Western States*, that the restriction of speech should be a last resort.

When these rules from the case law are applied to certain existing and proposed FDA regulatory actions, it is clear that there are strong grounds for the agency to reconsider its approach.

A discussion of six such topics follows. For each specific topic, references are provided to the numbered questions in FDA's request for comments.

Specific Comments

1. Dissemination of Enduring Materials and Support for Continuing Medical Education Regarding New/Unapproved Uses[5]

Under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), FDA has authority to review and approve new drugs and new claims for already approved drugs. FDA's exercise of its statutory authority under section 505 to require pre-market approval before a new drug is introduced into interstate commerce relates at base to the regulation of conduct, and does not in and of itself limit speech. As such, FDA's review and approval of new drugs does not implicate the First Amendment, and the evidentiary standards that Congress and the agency require for approval are not subject to First Amendment challenge. The First Amendment is raised, however, when FDA places restrictions on what someone may say about a drug, be it an unapproved drug or an unapproved use of an approved drug.

This section addresses one aspect of FDA's regulation of speech concerning unapproved uses of approved drugs: dissemination of enduring materials (journal reprints and reference texts) and support for continuing medical education (CME). These activities were at issue in the recent

[5] This section touches on Questions 1 (regulation of speech about drugs), 7 (speech on off-label uses), 8 (public health interests served by FDA speech-related regulations and alternative approaches), and 9 (FDA regulations, policies, etc. that should be revised) of the particular questions enumerated in FDA's request for comments.

Washington Legal Foundation (*WLF*) litigation. As discussed below, the agency has failed to take sufficient account of the First Amendment in crafting its post-*WLF* policies on the dissemination of enduring materials and support for CME.

a. The *WLF* Litigation

In the first decision in the *WLF* litigation, the court found that, under *Central Hudson*, FDA guidance documents on the dissemination of reprints and reference texts, and on support for CME (the "Guidance Documents"), infringed upon the right of pharmaceutical manufacturers to disseminate information relating to off-label uses because the Guidance Documents were more extensive than necessary to advance the government's legitimate interest in public health and safety. *Washington Legal Found. v. Friedman*, 13 F. Supp.2d 51, 72-73 (D.D.C. 1998) (*WLF I*).

A government motion to limit the scope of the injunction issued in *WLF I* was rejected, though it led the court to order additional briefing on the constitutionality of the Food and Drug Administration Modernization Act (FDAMA), which contained provisions that superseded two of the Guidance Documents at issue in the first case. *Washington Legal Found. v. Friedman*, 36 F. Supp.2d 16, 18 (D.D.C. 1999) (*WLF II*). After receiving the supplemental briefing, the district court concluded that FDAMA "largely perpetuates the polices held unconstitutional [in *WLF I*] and therefore may not be applied or enforced by FDA." *Washington Legal Found. v. Henney*, 56 F. Supp.2d 81, 84 (D.D.C. 1999) (*WLF III*).

On appeal, the government clarified its position that FDAMA and the Guidance Documents simply provide a "safe harbor" under which certain

forms of conduct are protected. *See Washington Legal Found. v. Henney*, 202 F.3d 331, 335 (D.C. Cir. 2000) (*WLF IV*). The FDA further stipulated that neither FDAMA nor the Guidance Documents "independently authorizes the FDA to prohibit or to sanction speech." *Id.* As a result, the appellate court noted that there was no longer a constitutional question in dispute and vacated the core holdings of the district court in *WLF I* and *WLF III*. *Id.* at 336-37; *see also Washington Legal Foundation v. Henney*, 128 F. Supp.2d 11 (D.D.C. 2000) (*WLF V*) (district court's previous injunction was vacated by the appellate decision).

b. FDA's Post-*WLF* Policy

FDA's stated post-*WLF* policy on the dissemination of enduring materials and support for CME has been equivocal, and does not take sufficient account of the First Amendment principles underscored in the litigation. For example, in a recent response to a citizen petition filed by WLF, FDA suggested (p. 4) that it could bring an enforcement action relying solely on the distribution of reprints or sponsorship of CME to demonstrate an unlawful intent to introduce a product into commerce for an unapproved use. At the same time, the agency also indicated (p. 6) that it would be "unlikely to initiate an enforcement action where the only evidence of an unapproved intended use is the distribution of enduring materials or sponsorship of CME." *FDA Response to Citizen Petition of Washington Legal Foundation*, Docket No. 01P-0250 (Jan. 28, 2002).

As stated, FDA's policy offers little concrete guidance to industry or to individual reviewers in the Division of Drug, Marketing, Advertising and Communications (DDMAC). More fundamentally, it is grossly inadequate in its

recognition of the First Amendment issues implicated, noting only (p. 2) that a manufacturer may raise a First Amendment challenge to an enforcement action. Nowhere else in its response to the WLF citizen petition does FDA fulfill the commitment the agency outlines at the beginning of its response when it states (p. 1) that "in . . . furthering the Agency's mission to protect the public health, it must respect the rights guaranteed by the First Amendment." As FDA crafts its post-*WLF* policies and considers individual enforcement actions related to the dissemination of enduring materials and support for CME, it must take substantially more account of the First Amendment and the decisions in the *WLF* case. This is not just a matter of the sound exercise of the agency's enforcement discretion, but a matter of constitutional imperative.

The district court decisions in *WLF* provide an appropriate starting place for developing a policy on enduring materials and CME support. In dismissing the appeal, the appellate court stated that it did not intend to "criticize the reasoning or the conclusions of the district court. As we have made clear, we do not reach the merits of the district court's First Amendment holdings." *WLF IV*, 202 F.3d at 337 n.7. Those district court holdings establish important boundaries on FDA's ability to restrict constitutionally protected commercial speech, and should be respected by the agency going forward, whether or not they remain legally binding.

c. The Importance of Information on Unapproved New Uses

The importance of disseminating information on unapproved new uses of an approved drug is well recognized. FDA has long championed the importance of ensuring that physicians have timely access to all current medical

and scientific information about a drug, including information on unapproved uses. As FDA's Deputy Commissioner for Policy testified to Congress, "FDA knows that there are important off label uses of approved drugs. In this context, it is important that physicians have access to accurate information about drugs." *More Information for Better Patient Care: Hearing of the Senate Comm. on Labor and Human Resources* [hereinafter *Better Patient Care Hearing*], 104th Cong., 2d Sess. 81 (Feb. 22, 1996) (prepared statement of William B. Schultz).

FDA's Associate Commissioner for Health Affairs similarly declared that the "principle for the FDA is that the very latest information that can be of value to physicians, pharmacists, and patients must be made available as soon as possible. Frequently, unlabeled use information is extremely important." Stuart J. Nightingale, Associate Commissioner for Health Affairs, *Unlabeled Uses of Approved Drugs*, 26 Drug Info. J. 141, 145 (1992).[6] FDA's position is shared by the medical community, which understands that "[i]t is imperative that physicians have access to accurate and unbiased information about unlabeled uses of prescription drugs." American Medical Association, Council on Scientific Affairs, *Report of the Council of Scientific Affairs: Unlabeled Indications of Food and Drug Administration-Approved* Drugs, 32 Drug Info. J. 1049, 1052 (1998).

Three prominent sources for information on the safe and effective use of a drug outside the approved labeling are peer-reviewed medical journals,

[6] *See also* 21 C.F.R. § 312.7(a) (rules for investigational new drugs are "not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media"); Nightingale, *supra* at 145 ("Now, physicians want to know more details about specific unlabeled uses since they are confident that in many cases they are the most appropriate therapeutic approach. The FDA applauds this . . . .").

independent reference texts (generally-available reference texts from independent publishers), and continuing medical education. According to the Director of what was then FDA's Bureau of Drugs, it is the medical literature and CME programs to which physicians turn for "new and interesting proposed uses for marketed drugs," and for "the many innovative ways in which experts use drugs in patient care, some of which are not in the package insert." J. Richard Crout, *In Praise of the Lowly Package Insert*, 29 Food Drug L. J. 139, 143 (1974). *See also* Nightingale, *supra* at 143 ("the medical literature, compendia, etc. may have more up-to-date information than the FDA official label").

Pharmaceutical manufacturers play a central role in the dissemination of this important medical literature and the support for CME programs. FDA itself has recognized that pharmaceutical companies may legitimately be involved in the dissemination of scientific information to physicians, even when such information pertains to the off-label use of the company's drugs. As the agency has explained,

> [s]cientific departments within regulated companies generally maintain a large body of information on their products. When health care professionals request such information, companies can provide responsive, nonpromotional, balanced, scientific information, which may include information on unapproved uses, without subjecting their products to regulation based on the information. This policy permits companies to inform health care professionals about the general body of information available from the company.

59 Fed. Reg. 59820, 59823 (Nov. 18, 1994); *see also* 60 Fed. Reg. 63384 (Dec. 8, 1995) (Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data).

The medical community agrees. The AMA's Council on Scientific Affairs believes that "educational value for physicians can be obtained if pharmaceutical manufacturers are allowed to disseminate reprints from journal articles, provided physicians can be assured that the information was independently derived, published in a reputable, peer-reviewed journal, and not altered by the manufacturer." AMA, Council on Scientific Affairs, *supra* at 1053.[7]

These prior statements of both FDA and prominent leaders in the medical community demonstrate that the public health is not served by suppressing the availability of journal reprints and reference texts, or limiting the ability of the industry to provide support for CME programs. To the contrary, any limitation on the ability of physicians to receive information on potentially important unapproved uses of approved drugs constitutes a serious impediment to patient treatment and the public health. And any restriction on the dissemination of truthful and non-misleading information must satisfy a high burden under the First Amendment.

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[7] *See also Better Patient Care Hearing*, *supra* at 77 (statement of Bernard Gersh, chairman of the Council on Clinical Cardiology of the American Heart Association) ("Physicians require better access to current, scientifically reliable and balanced information about drugs in order to make informed decisions for optimal treatment of their patients. Pharmaceutical and device companies should be permitted to disseminate copies of peer-reviewed scientific articles that report controlled clinical trials for off-label indications for their products"); *id.* at 21 (statement of Dr. Gregory H. Reaman, Director, Medical Specialty Services, Children's National Medical Center) ("Pharmaceutical and biotechnology companies obviously have an interest in supporting new uses of their products, but they also happen to be in the best position to share information with the physician community at the earliest possible time, when it may really make a difference in treatment options.").

d. A Constitutionally Sound Post-*WLF* Policy

Taking into account the recognized importance of information on unapproved new uses and the constitutional considerations highlighted in the *WLF* litigation, FDA's policy on the dissemination of enduring materials and support for CME should include, at a minimum, the following basic features:

- There should be no blanket prohibition on the dissemination of reprint or reference texts, or on support for CME, relating to the unapproved use of an approved drug. Similarly, the dissemination of enduring materials and support for CME alone should not be considered evidence of an unapproved intended use.

- FDA could potentially bring a misbranding case based on the dissemination of enduring materials and support for CME only if the information is proven to be false or misleading, or there is additional evidence from other company activities to establish that a drug manufacturer is introducing a drug into commerce for an unapproved intended use (*e.g.,* a concerted promotion campaign for an unapproved use).

- No enduring materials or CME may be presumed to be misleading. In a general guidance to industry, the agency might specify that enduring materials from peer-reviewed medical journals or independent medical reference textbooks, or independent CME programs, are presumed not to be false or misleading, but it cannot make the converse presumption. No speech may be prohibited unless the agency establishes that it is in fact false or misleading and has concrete support for its conclusion.

- Consensus standards, individual textbook chapters, journal supplements, review articles, and abstracts should be eligible for dissemination along with articles reporting on study findings. As with other enduring materials, the applicable test must be whether the materials are false or misleading.

- FDA may not prevent the communication of information where a disclaimer or disclosure can be used to ensure that the information is not false or misleading. The burden is on the FDA to prove that a disclaimer or disclosure cannot cure the misleading nature of a particular enduring material or CME program. If an appropriate disclaimer/disclosure would work,

then FDA must permit the speech with the accompanying disclaimer/disclosure.

FDA restrictions on speech in this area are open to constitutional challenge. As a threshold matter, a strong case can be made that the dissemination of enduring materials and support of CME programs is non-commercial speech, and that any government limitation imposed on such activities is subject to strict scrutiny. Reprints from peer-reviewed medical journals and other enduring materials and CME programs are certainly not commercial on their face. Nothing within the four corners of a reprint, a reference text, or a CME program "proposes a commercial transaction," and thus none of these activities fits within the core definition of commercial speech first set forth in *Virginia Board of Pharmacy*, 425 U.S. at 762.

This speech can be regarded as "commercial" only on the basis of the commercial identity and motivations of the speaker, a drug manufacturer who may of course be viewed as disseminating the materials or supporting the CME program as an indirect way to encourage a commercial transaction for one of its products. However, this approach violates the fundamental principles laid down by the Supreme Court that commercial speech "must be distinguished by its content," *Bates*, 433 U.S. at 363, and that the protection accorded speech may not be based on the "identity of the speaker" or a speaker's underlying motivations, *Pacific Gas & Elec. Co. v. Public Utilities Comm'n*, 475 U.S. 1, 8 (1986) (plurality opinion). Following this precedent, if the dissemination of enduring materials and support for CME programs is considered non-commercial

speech, few, if any, restrictions that FDA imposes on truthful and non-misleading information would survive.

The district court in *WLF* concluded that the dissemination of enduring materials and support for CME should be classified as commercial speech, although it noted that "this question is not an easy one." *WLF I*, 13 F. Supp.2d at 62-65. Even if that classification is correct, however, FDA cannot justify a more restrictive policy than the one outlined above. The district court's rulings make clear that the government cannot justify the imposition of blanket restrictions on the dissemination of reprints and reference texts, or on support for CME, by arguing that they are necessary to ensure that physicians receive balanced and unbiased information.

As the district court held, FDA "exaggerates its overall place in the universe" when it suggests that only scientific information it has evaluated is valid. *WLF I*, 13 F. Supp.2d at 67. Trained physicians are capable of evaluating journal articles, medical textbooks, and information presented at CME programs without FDA's assistance, particularly when they are accompanied by appropriate disclaimers making clear the status of any unapproved uses discussed. Similarly, any attempt to enforce a blanket prophylactic restriction on vital scientific and medical speech because the information may be misused would be fundamentally at odds with the First Amendment under *44 Liquormart*, 517 U.S. at 503, *Western States*, 122 S. Ct. at 1507, and other cases.

Whatever interest FDA has in preventing the dissemination of scientific information, broad restrictions against the dissemination of reprints and

reference texts or against support for CME programs simply do not directly and materially advance the government's interest, as required by *Edenfield*, 507 U.S. at 770-71. Indeed, this governmental interest is directly undercut by FDA's allowance of other speakers to disseminate the very same information, and the permission it grants even drug manufacturers to disseminate such information in response to unsolicited requests. There is a basic and impermissible irrationality to speech restrictions when the government permits other speakers to engage in the very same speech, or makes exceptions to allow the speech in some circumstances but not others. *Coors*, 514 U.S. at 488-89; *Greater New Orleans Broadcasting*, 527 U.S. at 194.

Moreover, there are obvious less restrictive alternatives to meet the government's objective of ensuring that the stream of commercial information "flows cleanly," and these alternatives must be pursued. *Western States*, 122 S. Ct. at 1507. The appropriate course for the agency is to take action against particular materials or programs that are false and misleading, or that are part of concerted campaigns to promote unapproved new uses, and to require reasonable disclaimers or disclosures as appropriate. No one questions FDA's continued authority to take action against particular disseminated materials or CME programs that are shown to be false and misleading, provided that there is a genuine basis for the agency's action.[8] Further, we know from *Pearson* that

[8] As the courts have held, the agency cannot simply declare that speech is misleading, *Ibanez*, 512 U.S. at 146 (government failed "to point to any harm that is potentially real, not purely hypothetical"), or restrict speech that it thinks "could, may, or might mislead," *WLF III*, 56 F. Supp.2d at 85.

disclaimers and disclosures are constitutionally preferred to the outright prohibition of speech. *Pearson*, 164 F.3d at 658.[9]

In its brief for the *WLF* appeal, FDA argued that it was free to restrict speech about unapproved uses because such speech is evidence of the illegal introduction of the drug into commerce for an "intended use" that FDA has not approved, and therefore is unprotected under the first prong of *Central Hudson*. This attempt to evade constitutional scrutiny and justify speech-restricting policies does not work. If the agency cannot regulate speech directly under the full *Central Hudson* test, it may not regulate it indirectly by using the speech as per se evidence of unlawful conduct.

The initial sale of the drug is certainly not illegal, because we are talking here about an approved drug covered by a new drug application (NDA) under section 505 of the FDCA. The use of an approved drug for unapproved uses is also not illegal. As discussed above, the government both accepts and encourages "off-label" prescribing. FDA would thus not be able to point to any illegal activities that are separate and distinct from the speech FDA is attempting to control. Using enduring materials or CME programs to declare a company's "conduct" illegal, and then citing the illegality of the conduct as a justification for

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[9] *See also Virginia Bd.*, 425 U.S. at 771 n.24; *Bates*, 433 U.S. at 375. There may be some cases where no disclaimer or qualifications could save a statement about the safety, effectiveness, or use of a drug from being false or misleading. For example, there may be one positive study about a new use of a drug, but a dozen negative studies showing that the drug is not effective for that use. However, these cases can be dealt with individually under the agency's well-established authority to take action against false or misleading statements.

restricting the speech, is circular and does not provide a basis for evading First Amendment scrutiny.

Restrictions on the dissemination of off-label information also cannot be justified by arguing that they are necessary to ensure that companies seek FDA approval of the new unapproved uses. Independent incentives exist for manufacturers to seek supplemental approvals. For example, FDA approval is important to ensuring that patients are able to obtain insurance reimbursement for the new use of a drug. *See, e.g.*, GAO, *Off-Label Drugs: Reimbursement Policies*, *supra*, at 5 ("reimbursement denials for such [off-label] use are . . . widespread"). FDA approval may also be an important factor in physician acceptance of a new therapy, and may be relevant to product liability issues. Thus, real incentives exist for companies to seek the approval of new uses. Companies may of course not seek approval of all new uses as they weigh the considerations in an individual case. But companies should not have their First Amendment rights held hostage by compelling them to pursue FDA approval in order to engage in protected speech. *WLF III*, 56 F. Supp.2d at 87 (requirement that companies pursue supplemental applications in order to exercise free speech rights "amounts to a kind of constitutional blackmail").

In light of these considerations, FDA should adopt a policy that, at a minimum, incorporates the concepts set forth in the injunction imposed by the district court in the *WLF* litigation. FDA should permit the dissemination of peer-reviewed reprints and independent reference texts with appropriate disclaimers

and disclosures. FDA should also permit the support of CME programs, including the suggestion of content or speakers.

2. Direct to Consumer Advertising[10]

Direct-to-consumer (DTC) advertising – like other forms of advertising and promotion – is commercial speech and is protected by the First Amendment.[11] Any restriction on DTC advertising must satisfy the *Central Hudson* test in order to pass constitutional muster. FDA has not imposed any special restrictions on DTC advertising to date. Nevertheless, FDA has recently been examining DTC advertising,[12] and various proposals to restrict this type of commercial speech have been proposed. Strong policy and legal reasons militate against the adoption of any such special restrictions on DTC advertising. FDA's current guidances on DTC advertising provide a workable approach without the undue restriction of speech, and should remain in effect.

As a matter of public policy, DTC advertising serves an important function by communicating health and treatment information to consumers. Direct-to-consumer advertising has been around for some time, first through print media and since the late 1990s through broadcast and other new media like the

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[10] This section focuses on Question 2 from the specific questions FDA enumerated in its request for comments.

[11] Of course, not all consumer communications are commercial in nature. The mere fact that communications are aimed at a consumer audience does not make them commercial. Educational and scientific information that does not propose a commercial transaction is non-commercial and is subject to strict protection under the First Amendment.

[12] *See* <http://www.fda.gov/cder/ddmac/dtctitle.htm> (presenting preliminary survey results).

Internet. Consumer advertisements can increase awareness of underdiagnosed and undertreated diseases, inform the public of new treatment options, promote compliance with physician-prescribed interventions, and prompt greater patient-physician dialogue.[13]

For example, in a statement issued to accompany a January 2002 report on DTC advertising the National Health Council[14] concluded : "After completing a thorough review of Direct-to-Consumer (DTC) prescription drug advertising, the National Health Council believes that DTC advertising is an effective tool for educating consumers and patients about health conditions and possible treatments." National Health Council, "Direct-to-Consumer Prescription Drug Advertising: Overview and Recommendations" (January 2002) and Accompanying Statement (available at www.nationalhealthcouncil.org/advocacy/DTC_paper.pdf & www.nationalhealthcouncil.org/advocacy/DTC.htm). This and other empirical research is reported by John E. Calfee, American Enterprise Institute, in a paper on "Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs" (July 8, 2002).

The concern has been raised that DTC advertising may cause inappropriate drug utilization by prompting consumers to take medicines that they

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[13] As the Supreme Court noted in a case dealing with lawyer advertising, advertising might "offer great benefits" to those who underutilize important services out of fear or ignorance. *Bates*, 433 U.S. at 376.

[14] The National Health Council is composed of voluntary health associations (e.g., the American Heart Association), professional and membership organizations (e.g., the AMA), other nonprofit associations (e.g., AARP), and large businesses, including pharmaceutical firms.

do not need. Empirical data on this important question are still being gathered. However, available data indicate that the concern is overstated and unfounded. For example, preliminary results from the 2002 FDA survey of consumers found that, among the minority of respondents who said advertisements had caused them to talk with a physician and ask for a drug, less than half said their doctor gave them the prescription drug they had asked about. The data are presented on FDA's Web site at http://www.fda.gov/cder/ddmac/dtctitle.htm. A 2001 survey by *Prevention Magazine* similarly found that 60 per cent of the consumers surveyed stated that their doctor recommended a non-drug therapy when they asked about an advertised prescription drug. E. Slaughter, "5th Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines," *Prevention Magazine*, 2002.

Of course, consumers may not obtain a prescription drug without a physician's prescription. Arguably, consumer advertisements strengthen the physician's role by encouraging patients to talk with their physicians and ask about appropriate treatment options. As the AMA has stated, "patients' health and medical care may benefit" from appropriate DTC advertising. American Medical Association, Council on Ethical and Judicial Affairs, "Direct to Consumer Advertisements of Prescription Drugs," 55 *Food and Drug Law Journal* 119, 124 (2000). "Patients informed about therapeutic possibilities are in a better position to participate in their own care." *Id.* Whether or not that is the case, physicians (or other authorized prescribers) are and will continue to be "learned

intermediaries" and help ensure that patients will not receive prescription pharmaceutical treatments unless appropriate.

Whatever the policy pros and cons, it is not constitutionally permissible to impose special restrictions on DTC advertising that is truthful and not misleading. It is inappropriate in particular to restrict truthful and non-misleading communications to consumers based on a concern that the information will lead to improper drug utilization. As the Supreme Court recently held in the *Western States* case, such a purported justification for a restraint on speech rests on "the questionable assumption that doctors would prescribe unnecessary medications." *Western States*, slip op. at 167.

Even if that questionable assumption were somehow correct, it is simply not lawful under the First Amendment to "suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients." *Virginia Bd.*, 425 U.S. at 773. As the Supreme Court has said, "[t]here is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and the best means to that end is to open the channels of communication rather than to close them." *Id.* at 770.[15]

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[15] *See also Bates*, 433 U.S. at 374-75 ("[T]he argument assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public. In any event, we view as dubious any justification that is based on the benefit of public ignorance.").

Among other things, preventing or restricting consumer advertisements to guard against improper drug use would be greatly overinclusive and underinclusive. Just like the restrictions on the advertising of pharmacy compounding services struck down in *Western States*, broad restraints on direct-to-consumer drug advertisements would be underinclusive in that they would not prevent consumers from getting access to volumes of drug information from speakers other than drug manufacturers (many of whom are altogether unregulated) through the Internet and elsewhere.[16] Accordingly, even if the sharing of drug information with consumers leads them to seek and physicians to prescribe drugs that in the opinion of other third parties the patients do not truly need, restraining advertisements by drug manufacturers would not stop improper prescribing. *See Western States*, 122 S. Ct. at 1508.

At the same time, the restrictions would be overinclusive. No one could plausibly argue that every direct-to-consumer advertisement leads to improper prescribing. Accordingly, the restraints would prevent legitimate and beneficial speech at the same time that they prevented the speech related to the concerns the government might have.

At the end of the day, as with other categories of commercial speech, there is a heavy burden to justify categorical rules preventing the speech. Instead, reasonable rules can be adopted to ensure that the information is truthful and not misleading. For example, rules might be adopted to ensure

[16] At best, then, restrictions on DTC advertising would provide "only ineffective or remote support for the government's purpose," in which case they "may not be sustained." *Central Hudson*, 447 U.S. at 564.

that risk information is communicated in a way that consumers will understand. It is not permitted, however, to prevent such speech in the first instance, or to single it out for special burdens because of a supposed concern that consumers (and their physicians) will act foolishly based upon accurately and fairly conveyed information.

3. Use of Trademarks and Tradenames[17]

Serious First Amendment issues are raised by at least two FDA policies regarding the use of trademarks and tradenames. The first policy is FDA's practice of countermanding determinations by the Office of Patents and Trademarks that two trademarks do not create a likelihood of confusion. The second policy is FDA's restriction on the use of multiple trademarks on products containing the same active ingredient, even where the trademarks themselves do not create a likelihood of confusion.

With respect to FDA's regulation of a trademark that it determines is likely to cause confusion, FDA assumes that excessive similarity among trademarks for pharmaceutical products is a significant cause of medication errors. FDA believes that it has the right to regulate the adoption of trademarks to prevent trademarks from being misleading, deceptive, or from causing confusion. Current FDA practice considers the potential of trademarks to mislead by using internal testing, which is the basis of FDA's opinion on the acceptability of a trademark for a particular product. In considering whether a

[17] This section touches on Questions 1 (regulation of speech about drugs), 8 (public health interests served by FDA speech-related regulations and alternative approaches), and 9 (FDA regulations, policies, etc. that should be revised) of the particular questions enumerated in FDA's request for comments.

trademark can mislead, FDA considers look-alike and sound-alike similarity to existing trademarks and non-proprietary names, as well as whether the proposed trademark suggests claims not established for the product.

The determination by FDA on these issues is based upon the opinion of a small group, which considers the results of a very limited sampling of personnel within FDA. The accuracy of such limited, subjective testing to determine whether a mark is truly misleading has not been validated, and, therefore, a finding that the mark is misleading is based on a perception that the mark could, may or might mislead.

This does not constitute the basis required to restrict speech in accordance with the First Amendment.[18] The FDA cannot substantiate that a proposed mark will mislead based upon a claim of look-alike, sound-alike possibility, where nonidentical marks are judged under a limited, subjective, nonscientific testing model. This is especially true in instances where the proposed mark has already been reviewed by the United States Patent and Trademark Office (PTO), and the mark has been registered on the Principle Register, thus obtaining the statutory presumption of validity and of the owner's right to use the mark in commerce. The PTO is the federal agency with primary responsibility for trademark issues. The action taken by the PTO in registering a mark, and its determination that it will not likely cause confusion, should be

[18] Trade names and trademarks communicate information to consumers about the type and quality of a given product, and thus are a form of constitutionally protected speech. *See, e.g., Friedman v. Rogers*, 440 U.S. 1, 11 (1979) (a trade name, which generally receives the same protection under the law as trademarks, is protected speech under First Amendment).

accepted by FDA, unless it can show by the strongest of evidence that the PTO was mistaken on the issue of likelihood of confusion.

The FDA's current, questionable practice of regulating the adoption of trademarks does not address factors that contribute significantly to medication errors such as poor physician handwriting, poor auditory conditions during verbal orders, incomplete prescribing information, distractions in the pharmacy or hospital, poor lighting, inadequately trained staff, and over-worked personnel. There are alternative, less restrictive means of addressing the problem of medication errors that are more likely to achieve the government's goal.

For example, FDA itself has long recognized that the use of appropriate disclaimers could reduce or eliminate the possibility that a trade name could mislead. A regulation proposed in 1974 would have required that FDA consider whether the use of disclaimers could eliminate the possibility that a trademark might be misleading before it orders the excision of the mark. *See* 39 Fed. Reg. 11298 (Mar. 27, 1974). FDA explained that

> [i]t is the policy of the Food and Drug Administration, in accordance with principles laid down in the courts, to require excision of a brand name only where nothing short of excision would eliminate the possibility of deception, and to permit retention of a brand name where either permanent qualification of the name or prominent public disclosure of the change in the product for a significant period of time is sufficient to inform the public of the change . . . .

Id. Although this regulation was never formally adopted by FDA, the agency has never retracted its analysis.[19] That analysis applies with even greater force today

[19] This proposed regulation was withdrawn by FDA as part of the agency's withdrawal of 115 proposed rules that it had not had an opportunity to finalize.

in light of evolving First Amendment case law. If there are steps FDA can take to ensure that trademarks are not misleading short of prohibiting use of the marks, they must do so.

As to the use of multiple trademarks on products containing the same active ingredient, we understand that the Center for Drug Evaluation and Research is developing a Manual of Policy and Procedures (MaPP) and a Guidance relating to its review and approval of trademarks under which the agency "strongly discourages" the adoption of more than one trademark by the same sponsor for the same active ingredient even when the sponsor submits a new NDA to support a new indication or formulation. Additionally, the Center for Biologics Evaluation and Research (CBER) has recently issued a Manual of Standard Operating Procedures and Policies (SOPP 8001.4) (Aug. 15, 2002), which states that CBER will not accept a proposed proprietary name if another name already is being used for an essentially identical product. The prohibition of the use of multiple trademarks is also a violation of First Amendment rights. The arguments in support of this proposition were the subject of a separate Position Paper that PhRMA submitted to the Office of General Counsel on April 16, 2002. The Position Paper is attached to these comments. Accordingly, the arguments on this important First Amendment issue will not be repeated further here.

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56 Fed. Reg. 67440 (Dec. 30, 1991). FDA has made clear that the withdrawal of a rule as part of this effort does not indicate that FDA disagrees with the substance of the proposal. 56 Fed. Reg. 42668 (Aug. 28, 1991).

4. Press Releases[20]

The agency treats press releases that discuss an approved drug product as promotional labeling under 21 C.F.R. § 202.1(l)(2). *See, e.g.*, Letter to Industry from Carl C. Peck, Director Center for Drug Evaluation and Research (July 24, 1991) (a press release is promotional labeling if it "makes any representation or suggestion related to the use of an identifiable drug product" and it is issued by or on behalf of an NDA holder). Given the agency's position, press releases for approved products must satisfy all of the rules that apply to promotional labeling, and truthful and non-misleading statements about a drug that otherwise might be communicated in a press release are prohibited. Similarly, FDA regulates press releases about investigational drugs under 21 C.F.R. § 312.7, which prohibits the "promotion" of investigational new drugs. Although the agency permits press releases to include limited statements about scientific findings from studies on new uses, the agency strictly prohibits broader representations or suggestions about uses that remain unapproved.

For example, DDMAC has issued letters based solely on statements in a press release that describe a drug as "the first of a new class" and then describe the mechanism of action for the drug. DDMAC similarly has issued letters for press releases that describe "encouraging preliminary studies" for drugs, and for press releases that summarize findings from clinical trials.

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[20] This section touches on Questions 1 (regulation of speech about drugs), 7 (speech on off-label uses), 8 (public health interests served by FDA speech-related regulations and alternative approaches), and 9 (FDA regulations, policies, etc. that should be revised) of the particular questions enumerated in FDA's request for comments.

Whatever the merits of the particular letters that DDMAC has issued, they reflect a broader FDA policy under which all but the most limited statements about unapproved new uses in press releases are strictly prohibited. This policy is overly restrictive and impermissibly burdens speech.

FDA's treatment of press releases as promotion is rooted in its extraordinarily broad definition of labeling. Under the FDCA, labeling is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." FDCA § 201(m). In *Kordel v. United States*, the Supreme Court held that this definition does not require physical attachment for material to be considered as "accompanying" an article, provided there is a sufficient relationship between the material and the article. 335 U.S. 345, 350 (1948). This concept of labeling is quite broad, to be sure. However, FDA has stretched the concept well beyond the broad definition in *Kordel* to reach press releases intended to inform the public at large about drug studies and drug development milestones. If statements about study findings and drug development programs can be said to "accompany" a drug, then it is difficult to see what meaning is left in the statutory concept.

Moreover, if FDA is going to stretch the definition of labeling, it must be mindful of the First Amendment. Press releases are of course a form of speech, but more than that they should be treated as non-commercial speech and accorded the highest protection under the First Amendment. For example, if a press release announcing the results of a phase III study states that the drug

represents a potentially promising new therapy for some cancer, it cannot fairly be concluded that the press release is proposing a commercial transaction. Although some press releases may perhaps propose a commercial transaction, general communications to the media or public about drug studies or drug development events do not propose a commercial transaction, and thus should not be considered commercial, even if they contain suggestions about potential new product uses.

If press releases are treated as commercial speech, FDA would still have to justify any restrictions it imposes under the *Central Hudson* requirements discussed at length above. Its current restrictions do not meet this test, because they prohibit truthful and non-misleading statements in press releases solely because they relate to unapproved uses. The prohibition of these statements in the context of a press release is particularly hard to justify. Take, for example, the announcement of findings on a prominent study for a new AIDS therapy. Under FDA's current policies, the drug's manufacturer would be extremely limited in the statements it could make about the study in a press release. These restrictions would not apply to physicians, researchers, patient advocates, and others, who presumably would fill the news media with commentary on the study. There could thus be no legitimate government interest served by preventing the manufacturer from including information in a press release beyond that currently allowed by the agency, provided that the information is truthful and not misleading. No harm whatsoever would be inflicted on the public health.

Moreover, there are far less restrictive ways to promote the government's interests. For example, disclaimers could be required to make clear exactly what evidentiary support exists for the statements being made, and to make clear that FDA has not approved the information. References to approved drug labeling could be required where available. Additionally, it could be required that any known negative information be referenced along with positive information. This tracks the approach set forth by the D.C. Circuit in *Pearson* and by the district court in *WLF*.

These less restrictive approaches would also preserve the government's interest in ensuring that there remains an incentive to seek supplemental product approvals. For example, only by seeking and obtaining an approval would a company be able to omit the required disclaimers and qualifications, and promote the new information about the drug. Incentives also exist to seek FDA approval in order to ensure that the drug will be reimbursed by insurers, and to guard against product liability risk, as mentioned above.

To the extent that the incentive to seek supplemental approvals might be diminished by some measure if FDA revises its policies for press releases, that would still not justify FDA's current restrictive policies. As the Supreme Court stated in *Central Hudson* itself, "We review with special care regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy." 447 U.S. at 566 n.9. In *Central Hudson*, the New York Public Service Commission banned promotional advertising by electrical utilities to promote the nonspeech-related policy of encouraging energy

conservation. Here, FDA cannot impose overly restrictive rules on press releases to advance the nonspeech-related policy of encouraging supplemental drug applications.

In *Central Hudson*, the Court suggested that a less restrictive approach could be employed to promote energy conservation, such as requiring utilities to include information about the efficiency and expense of an advertised service. *Id.* at 571. So, too, here, FDA can promote its interest in supplemental drug approvals by requiring companies to include prominent statements about the absence of FDA approval in any press release that discusses an unapproved use. This alternative approach to FDA's current policies encourages more speech rather than less while still serving the potential governmental interests underlying the existing policies.

For these reasons, FDA should reconsider its current policies on press releases. Those policies are overly restrictive and do not square with First Amendment considerations. Neither FDA's regulation on the promotion and commercialization of investigational drugs (21 C.F.R. § 312.7), nor its rules on promotional labeling for approved drug products (21 C.F.R. § 202.1), provide guidance to distinguish permissible versus impermissible press releases concerning unapproved drug uses consistent with the First Amendment.

5. Professional Meeting Booths[21]

For the same reasons that FDA's current policies on press releases do not withstand constitutional scrutiny, some of the agency's policies on scientific booths at professional meetings are overly restrictive and do not square with the First Amendment. These policies are illustrated by letters that DDMAC has issued based solely on the dissemination of qualified scientific information on unapproved uses at exhibit booths. For example, DDMAC has charged that statements regarding "the potential" and "goal" of investigational new therapies constitute evidence of the promotion of approved drugs for unapproved uses and the commercialization of investigational new drugs, and therefore violate the law. Similarly, DDMAC has taken issue with allegedly conclusory statements regarding the evidence of effectiveness observed in investigational trials.

FDA may rightfully take action against truly promotional information disseminated through meeting booths, where the claims made go beyond the available evidence and therefore can be shown to be false or misleading. However, so long as the information provided is appropriately qualified, and true and not misleading, it is protected by the First Amendment. FDA cannot enforce a blanket prohibition on the provision of scientific information through professional exhibit booths solely because the information concerns an

[21] This section touches on Questions 1 (regulation of speech about drugs), 7 (speech on off-label uses), 8 (public health interests served by FDA speech-related regulations and alternative approaches), and 9 (FDA regulations, policies, etc. that should be revised) of the particular questions enumerated in FDA's request for comments.

unapproved use. Importantly, FDA should always consider the least restrictive alternative to outright suppression.

FDA has a particularly heavy burden under the First Amendment to restrict information presented at professional meeting booths that is genuinely scientific in nature. Statements that summarize recent study findings, or identify the potential and objectives for investigational new therapies, do not propose the purchase or sale of the products, some of which are not even available commercially yet. These communications are far removed from the definition of commercial speech, and therefore should be accorded heightened First Amendment protection. If information provided through meeting booths is classified as commercial speech, FDA may take action in particular cases, but only if the action serves an important governmental interest, FDA can specifically establish that the information being provided is in fact false or misleading, and disclaimers or other less speech-restrictive alternatives cannot be utilized.

6. Other Regulations and Policies Requiring Reconsideration[22]

Various other FDA regulations and policies that erect categorical or overly rigid prohibitions on particular types of drug promotion and other communications raise constitutional issues of the type discussed extensively in these comments. These include, for example, the categorical prohibition on reminder advertising and labeling for drugs with a boxed warning;[23] the rule

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[22] This section addresses Question 9 (FDA regulations, policies, etc. that should be revised) from FDA's request for comments.

[23] 21 C.F.R. §§ 201.100(f) & 202.1(e)(2)(i).

prohibiting all statements of "differences of opinion with respect to warnings;"[24] the restrictive rules on permissible quality of life claims;[25] and the rule against using pre-approval institutional ads after a "coming soon" piece (and vice versa).[26] Detailed comments on these specific topics are not provided here because the analysis tracks that provided for the other topics that have already been discussed. As with the topics discussed above, FDA may only restrict speech if it can provide concrete evidence that the speech is false or misleading, or if it can establish that there are not other less restrictive ways to advance the legitimate government interests that are implicated.

Conclusion

PhRMA appreciates the opportunity FDA has provided to submit these comments. We look forward to a continued dialogue with the agency and other stakeholders on the critical First Amendment issues that are raised by FDA's regulation of speech about pharmaceutical products.

Attachment

- PhRMA Position Paper on Multiple Trademarks, submitted to FDA April 16, 2002

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[24] 21 C.F.R. § 1.21(c).

[25] *See, e.g.*, DDMAC, Draft Principles for the Review of Pharmacoeconomic Promotion (Mar. 20, 1995).

[26] DDMAC Pre-Approval Promotion Guidance (Apr. 1994); Division of Drug Advertising and Labeling Pre-Approval Promotion Guidance (Aug. 1986).

PhRMA

POSITION PAPER ON MULTIPLE TRADEMARKS

PREPARED BY THE TRADEMARK SUBCOMMITTEE
OF THE LAW SECTION IP/PATENTS FOCUS GROUP
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

EXECUTIVE OVERVIEW

Among the new initiatives at CDER regarding the review of trademarks is an effort to reduce the number of trademarks by making it extremely difficult for an innovator company to use more than one trademark on products containing the same active ingredient. We understand that CDER is developing a Manual of Policy and Procedures (MaPP) and a Guidance relating to its review and approval of trademarks that contain language that "strongly discourages" the adoption of more than one trademark by the same sponsor for the same active ingredient even when the sponsor submits a new NDA to support a new indication or formulation. The release date for the MaPP and Guidance is uncertain, but the industry concern is that the Division of Medication Errors and Technical Services (DMETS) has already adopted this practice in handling current requests for review.

The PhRMA Trademark Subcommittee (PTS) respectfully, but vigorously, opposes CDER's discrimination against innovator drug companies by adoption of this new position, which would: disrupt an effective channel of communication with patients and health care providers; violate First Amendment speech rights; infringe Fifth Amendment property rights; constitute arbitrary and capricious action under the Administrative Procedure Act; contravene the statutory presumption of the right to use registered trademarks; and violate Article 20 of TRIPS. Although the proposed restriction on multiple trademarks is described as an effort to address the problem of medication errors, it is not materially relevant to either that problem or its solution. The proposed action is inappropriate because it is not reasonably calculated to meet CDER's interests and may create more patient problems than it might prevent. There are other and much more effective ways of addressing the problem of medication errors, short of unconstitutional action.

In this Position Paper, the PTS: (i) offers background information on the nature of trademarks and medication errors in the pharmaceutical industry, and CDER's role in reviewing and approving trademarks; (ii) presents CDER's publicly stated position on multiple trademarks, the industry's perspective, and an analysis of the legality of the FDA's position, which threatens to weaken the trademark system and deny many patients the benefits of continuing clinical research; and (iii) asks FDA to reject a de facto arbitrary ban on multiple trademarks in favor of CDER's prior practice of

treating multiple trademarks for products that contain the same active ingredient the same way it treats other trademarks coming to the Agency for review.

Prescriptions in the US are increasing at a rapid rate. The number of retail prescriptions sold between 1992 and 2000 increased by about 50% and reached nearly 3 billion at the start of the new millennium. While the great majority of prescriptions are dispensed and administered error free, there is a very small percentage that fall victim to human or system error, resulting in medication errors. Both the pharmaceutical industry and CDER share a common goal to minimize or prevent patient harm resulting from medication errors without denying or deterring patients from the benefits of prescription medications. Claiming authority under the Federal Food, Drug, and Cosmetic Act, CDER has implemented steps to review and approve drug product names and trademarks that appear in drug product labeling. The industry, working cooperatively with CDER, uses a variety of resources to develop distinctive trademarks that help the medical community avoid medication errors. However, given the nature of these errors there is no evidence that restricting a drug company's right to multiple trademarks will meet this objective; in fact, it will do more harm than good by removing an effective means of communicating with patients and health care providers.

TRADEMARKS IN THE PHARMACEUTICAL INDUSTRY

Trademark Definitions

In 15 U.S.C. § 1127, the Lanham Act defines a trademark as including "any word, name, symbol, or device, or any combination thereof, used by a person . . . to identify and distinguish his or her goods . . . from those manufactured or sold by others and to indicate the source of the goods, even if that source is unknown."

Trademarks are symbols of the innovation, manufacturing skill, integrity, and reputation of the company, and the guarantee of the quality of the company's products. Unlike a generic or non-proprietary name, which can be freely used by all companies, a trademark can only be used to distinguish the products of the owner company or its licensee.

Beyond their role as a source indicator and guarantee of quality, trademarks in modern commerce and communication have emerged as an efficient communication device that helps the owner speak to customers and transmit a large amount of information. Trademarks encompass not only consumer awareness, but also perceived quality, customer loyalty, and a rich set of associations. Trademarks serve consumers by communicating information about the product that tends to reinforce their prior experience. Trademarks also serve as an incentive to companies to maintain or improve the quality of their products, thereby creating a positive cycle of consumer satisfaction and product improvement. The net result is a strong trademark identity that benefits the company and assists the patient and the medical field in identifying, distinguishing and understanding the substantial number of medications on the market today.[1]

[1] For more background on the degree to which trademarks embody the quality, skill, and integrity of a company and its products, see generally Jerre B. Swan, Sr. et al., *Trademarks and Marketing*, 91 Trademark Rep. 787 (2001).

Legal Significance of Trademarks

The legal protection surrounding trademarks has its origins in the common law. The basic principle of law underlying trademark rights is that no one has a right to represent his goods as the goods of another. Trademark rights are based on prior and continuous use of the trademark in commerce in connection with the trademark owner's goods. As trademark law has developed in this country, the right in a trademark has come to be seen and treated as a property right. See Trade-Mark Cases, 100 U.S. 82, 92 (1879). The right to adopt and use a trademark to distinguish one's goods from those of another is recognized by the US Supreme Court. See id.

The first federal trademark statute was passed in 1870, but it was the Act of 1905 that provided the legal basis for much of the modern trademark law in the US. The modern federal trademark statute is the Lanham Act of 1946 (United States Code, Title 15, Chapter 22 – Trademarks). The intent of the Lanham Act is:

> to regulate commerce within the control of Congress by making actionable the deceptive and misleading use of marks in such commerce; to protect registered marks used in such commerce from interference by State, or territorial legislation; to protect persons engaged in such commerce against unfair competition; to prevent fraud and deception in such commerce by the use of reproductions, copies, counterfeits, or colorable imitations of registered marks; and to provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations.

15 U.S.C. § 1127.

The Lanham Act was amended in 1988 by the Revision Act, which provided an alternative means to establish trademark rights. Under the Revision Act, one can file an "intent to use" trademark application if the applicant has a bona fide intent to use the trademark on the goods described in the application.

Trademark registration under the Federal statute establishes benefits beyond those in common law. Among those other benefits, federal registration provides prima facie evidence of the registration's validity, of the registrant's ownership of the trademark, of the registrant's exclusive right to use the mark in connection with the goods specified in the registration certificate, and of the right, after continuous use of the trademark for five years after registration, to have the registration become incontestable. When a mark achieves incontestable status it constitutes conclusive evidence of the registrant's exclusive right to use the trademark in commerce for the identified goods, subject to certain defenses.

Trademark Development

Trademark development and registration is a well-thought out process with many participants who are dedicated to avoiding confusion among trademarks. Adoption of a trademark is more than creating a new word that is immediately placed on a product for sale. This is particularly so in the pharmaceutical industry, where the products are heavily regulated and the market is global. Global

trademarks are preferred because many doctors come to the US for training and become exposed to the latest pharmaceutical products. When they return to their home countries, they often look for the availability of these products there. International travel by consumers, international medical conferences, and the proliferation of the Internet are additional factors that support the need for global trademarks.

Before considering whether to adopt a trademark, a company must first make sure the mark: (i) is not confusingly similar to a mark being used by someone else in all the countries where the mark will be used; (ii) is easily pronounced in each country of use; and (iii) is linguistically and culturally acceptable. Particular care must be taken when adopting a new mark for a pharmaceutical product because confusion among pharmaceutical trademarks is a safety concern as well as a legal one.

Development of a trademark for a pharmaceutical product usually begins at about 3 to 4 years before New Drug Application (NDA) approval. Often a specialized company with experience and demonstrated creativity in creating new names is selected to help. Hundreds of names are created before the list is whittled down to a manageable number of candidates. The goal is to select a trademark that is acceptable for the product, will not mislead in any fashion, is not confusingly similar to any prior trademark, and can be safely used by all those who will be involved in the prescribing, dispensing and use of the product.

The legal clearance cycle begins with extensive legal searches of various databases including federal and state trademark records, common law databases and references, and Internet usage, including domain names. These searches are not limited to the US, but are extended to the European Union (EU), Canada, Australia, and key countries in Central and South America, Africa and Asia. The test for availability that the attorney uses when reviewing the searches is likelihood of confusion. The degree of similarity in appearance, pronunciation, connotation, goods, and channels of trade are involved. In deciding whether trademarks are likely to cause confusion, consideration must be given to the impression created by each mark as a whole in the marketplace.

The trademark attorney reviews a mound of data containing marks with some level of potential for phonetic, visual, or connotative similarity to the target mark. After a careful examination and evaluation of all available data, a professional judgment is made on the likelihood that the mark will be available for use and registration because it is distinctive from all other marks. Many pharmaceutical companies include in the clearance process for proposed trademarks a review by independent practicing pharmacists and other practicing health care providers who carefully evaluate the proposed marks for medication error potential. Such a review takes into account the fact that the degree of similarity between two trademarks is dependent not only on the similarity of the trademarks in appearance and sound, but also when viewed as a handwritten prescription or hospital order. It is also evaluated in the context of dosage form, dosage strengths, dosage regimens, route of administration, etc. This independent evaluation from a clinical perspective offers additional insight and experience on whether a mark can be used safely or may be prone to confusion and possible medication errors. The industry has a number of resources available to obtain evaluations of the type described above.

Trademark Registration

In the US, the trademark application is filed with the US Patent and Trademark Office (PTO). The application contains a drawing of the mark (in the case of a word mark, the drawing often consists of the word typed in all block letters), a specimen of the mark as actually used (if the mark is in use at the time of filing), and the statutory filing fee. An Examiner in the PTO examines the application to see that it complies with all formalities, then conducts his own search to determine if the applied for mark is likely to cause confusion with prior registered and applied-for marks. If the Examiner is satisfied that the application is in proper form and the mark can be used without being likely to cause confusion with existing marks, the application is published in the PTO's weekly-published Official Gazette (OG). This OG publication gives the public and other companies an opportunity to oppose the application if any person or company believes it would be damaged by the issuance of the registration. If no opposition is filed in the time allowed (thirty days in the US), a Certificate of Registration will be issued for the application or, in the case of an Intent to Use application, a Notice of Allowance will be issued. Most companies review the OG for confusingly similar marks, and the opposition process in the US is an additional opportunity to weed out potentially confusing trademarks through this practice of self-policing.

In the US, the registration cannot issue until the trademark is put into use. Generally, trademark use on goods means the goods are sold with the trademark clearly affixed to the goods or to packaging of the goods. The legislative history of the Revision Act supports the use of a pharmaceutical trademark on a clinical investigation shipment as constituting legal use in commerce to warrant registration of a trademark. Hence, it is likely that the sponsor of an Investigational New Drug (IND) application or an NDA can, and in many cases will, obtain a federal registration of a trademark before approval of the NDA.

Trademarks for important pharmaceutical products are often registered in over one hundred countries. Confidence that a trademark is globally available takes a great deal of time and financial resources. The legal searches and evaluations can take up to one year and more. The registration process can take anywhere from one year in the US to 18 months in the EU and up to two years in Japan. Issues raised with the application can extend these estimates. It is only after the trademark begins to register in major markets throughout the world that the trademark owner will know that the trademark will likely succeed as a global trademark. As noted earlier, most companies with an interest in obtaining a global trademark begin the process at least three to four years before product approval.

The trademark development and registration process described above has been developed in the US and abroad over more than a hundred years as a process with many safeguards to predict whether a new trademark has the potential to cause confusion with trademarks already in the marketplace.

MEDICATION ERRORS

Background

Medical errors are a serious problem in any health care system. Medical errors include surgical errors, diagnostic errors, adverse effects from drugs, and any number of other unintended actions that result in patient harm or death. Medication errors relating to the misprescribing or misdispensing of

medications are a relatively small subset of medical errors. The pharmaceutical environment is very different from the usual consumer experience. The doctor either prescribes in writing (which may be handwritten, preprinted, or by computer) or verbally with call in orders. The pharmacist dispenses and the patient-consumer picks up the product and consumes it. In a hospital setting, medications are often delivered to the patient by a nurse from a medication cart. Error or confusion can result from a combination of a number of different factors: bad handwriting, poor auditory conditions when receiving verbal orders, incomplete prescribing information, distractions in the pharmacy, poor lighting, inadequate training of staff, over-worked personnel, similarity in drug names, etc. Medication errors are tracked by a number of voluntary programs in the U.S. The most well known are discussed briefly below.

The Institute for Safe Medication Practices (ISMP) was founded in 1975 by Neil Davis and Michael Cohen for the purpose of helping professionals avoid medication errors. The ISMP began a medication error-reporting program which encouraged pharmacists and others to voluntarily report medication errors or concerns about name similarity as a means to help others prevent or minimize medication errors. The United States Pharmacopeia (USP) is the official standard-setting authority for the manufacture of pharmaceutical compounds and also offers a wide variety of reference books and other information for health care professionals and consumers. The USP became involved in the Medication Errors Reporting Program in 1991 and provided the administrative resources needed to collect reports of errors and error concerns from practitioners. The current USP database of reports contains about 14,000 entries.

The FDA MedWatch program is another program designed to collect medication errors. Practitioners or any member of the public can report a medication error to the MedWatch Program, where it is entered into the Program's database. The current USP/ISMP database is shared with the FDA MedWatch database and the various companies whose products are the subject of reports. The data, and information from subsequent investigation of selected reports, are used by ISMP and others to structure educational programs to help practitioners avoid the kinds of errors that are the subject of the reports.

The USP MedMARx program is a hospital-based, subscriber-paid error reporting program designed to use electronic technology to help hospitals collect data on medication errors in a standardized format. Participating hospitals can access the data to compare error rates and related information. A number of institutions and organizations, including the Premier Hospital Chain and AdvancePCS, have medication error programs under way or in development.

It should be noted that these voluntary reporting programs are not designed primarily to provide data to analyze all of the circumstances surrounding the cause of the errors, e.g. poor handwriting, distractions in the pharmacy, name similarity, etc. Rather, they only report the errors as a warning to others. It is axiomatic that every name/name mix up will involve two drug names as a means to identify the mix up. This does not mean that name/name similarity is the root cause of the error. For example, the JAMA article: "Factors Related to Errors in Medication Prescribing," published in January 1997 (Vol 277, No. 4), reported on 2103 medication errors thought to have potential clinical importance in a hospital setting during a period of a year. The authors identified 696 of these errors as having the potential for adverse patient effects. Of these 696 medication errors, 13.4% were stated to be linked to nomenclature factors (incorrect drug name, dosage form or abbreviation). This grouping together of

separate and disparate causative factors is common in medication error reporting. It is not possible to use statistics available from this and many other studies, or data from the USP and ISMP, to determine to what extent, if any, medication errors are attributable to name/name similarity.

CDER Involvement

The CDER interest in trademark review can be traced back to the 1970s, when chemistry reviewers were asked to include nomenclature reviews as part of their evaluation of the NDA assigned to them. There are anecdotal reports of concerns expressed during the NDA review process that resulted in name changes to satisfy CDER concerns.

The legal basis for CDER involvement flows from section 502(a) of the Federal Food, Drug, and Cosmetic Act, which provides that a drug "shall be deemed to be misbranded" if "its labeling is false or misleading in any particular," and section 505(d)(7), which provides that an NDA is not approvable if, "based on a fair evaluation of all material facts," the labeling submitted in the NDA "is false or misleading in any particular." 21 U.S.C. §§ 352(a) and 355(d)(7). Congress intended that this evaluation be made based only on "objective facts of record" showing that the labeling is "demonstrably false or misleading" (see 108 Cong. Rec. 21066, 1962). It seems clear that CDER's effective prohibition of multiple trademarks does not meet this standard.

In 1990, CDER created the Labeling and Nomenclature Committee (LNC) to facilitate the review of trademarks that takes place within each of the CDER reviewing divisions. The LNC was chartered to provide recommendations to the various reviewing divisions regarding the use of trademarks. The responsibility for ultimate acceptance or rejection of trademarks rests with the reviewing division.

Certainly, today, CDER has an increased interest in medication errors, prompted in part by many more products and prescriptions and the attention drawn to medication errors by various articles and the 1999 Institute of Medicine ("IOM") Report, "To Err is Human: Building a Safer Health System." The IOM Report contained a comprehensive review of the US health care system with a focus on medical errors. See "Summary of Report: To Err is Human: Building a Safer Health System", available at http://www.iom.edu/iom/iomhome.nsf/Pages/2000+Reports.

In October 1999, the responsibility for trademark review was transferred from LNC to the Office of Postmarketing Drug Risk Assessment (OPDRA). The OPDRA approach to trademark evaluation went beyond the LNC process for trademark review and evaluation by involving to a greater degree prescription testing of proposed new trademarks. The sponsor requests a review and provides information about its product for which the trademark is intended, information such as dosage form, amount and regimen and indications and contraindications for the drug. The OPDRA staff reviews the data, prepares written prescriptions and verbal orders for the proposed trademark, then forwards the information to volunteers within the Agency who perform an evaluation exercise. The OPDRA staff evaluates data from the volunteers and from other sources, conducts a risk benefit analysis, then makes a recommendation to the reviewing division.[2] The OPDRA process shares similarities with various error identification services that were in place before the creation of OPDRA.

[2] For a detailed description of the review process, see Jerry Phillips, *The Name Game. New Realities at FDA*, in Pharmaceutical Executive pp 66-69 (July 2000) (article by Associate Director at OPDRA who heads up the review function).

On February 22, 2000, the Clinton Administration's Quality Interagency Coordination Task Force (QuIC) endorsed recommendations of the IOM Report and directed the FDA to develop new standards to help prevent medical errors caused by proprietary drug names. See White House Press Release, "Clinton-Gore Administration Announces New Actions to Improve Patient Safety and Assure Health Care Quality," February 22, 2000. The PTS is eager to work with the FDA and bring its expertise to the job of developing new standards.

The FDA recently announced a number of organizational changes, one of which was the creation of the Division of Medication Errors and Technical Services (DMETS). DMETS is one of three divisions in the newly created Office of Drug Safety (ODS). It has taken over the responsibility of the former OPDRA organization. See *Office of Drug Safety Annual Report for Fiscal Year 2001, available at* http://www.fda.gov/cder/Offices/drugsafety/AnnRep2001/annualreport2001.htm.

Trademarks Support Medication Safety

The PTS shares the same goal as CDER: minimizing and to the extent possible eliminating medication errors. The PTS applauds the work done by CDER and other organizations, like ISMP, in heightening awareness of the problem and developing tools that assist in the trademark selection process. In the view of PhRMA trademark experts, pharmaceutical trademarks support safe medication use because they are designed to maintain a distinctive separation from all other names and trademarks. As noted earlier, there are upwards of 3 billion doctor directed medication transactions annually in the US. The vast majority of these transactions are error-free.

One way to appreciate the efficiency and value of trademarks in the complex health care system that still relies in large measure on paper and pen technology is to consider alternate approaches to drug identification. There are essentially two alternates available: use of only nonproprietary names (many of which are required to be very similar because of the system of naming used in assigning nonproprietary names to new active ingredients) or use of names that consist of some pseudo-random variation of alphanumeric characters (which characters could easily be transposed). In either of these alternatives, the experience with human factors suggests that miscommunication would increase and with it, the number and rate of medication errors. Alternates to the paper and pen methods, such as bar coding and convenient hand-held devices, offer promise of further reducing name-related medication errors.

A large part of the success of pharmaceutical trademarks in error-free prescribing, dispensing and administering is due to the rigorous review and analysis conducted by pharmaceutical companies and the PTO registration process that produces trademarks that have been put through a series of evaluations designed to create a unique trademark that can be safely used and is free of confusing similarity to any other trademark. In Lambert, "Descriptive Analysis Of The Drug Name Lexicon", Drug Information Journal, 2001, the authors provided "a descriptive analysis of the drug name lexicon, with a primary emphasis on drugs marketed in the United States." The authors conclude in part, "contrary to some impressions that the drug lexicon is getting too crowded, the evidence presented here suggest that most pairs of drug names are not similar to one another (at least using measures of orthographic or spelling similarity)."

MULTIPLE TRADEMARKS

CDER's Position

CDER's prior practice has been to show a willingness to approve multiple trademarks when requested by the sponsor. As late as 2001 CDER granted approval for different trademarks for multiple NDAs for the same patented drug. Examples of such are:

ENTOCORT EC (2001)/RHINOCORT (1994)/PULMICORT (1997) (budesonide);
SARAFEM (2000)/PROZAC (1988) (fluoxetine);
PROPECIA (1997)/PROSCAR (1992) (finasteride);
ZYBAN (1997)/WELLBUTRIN (1989) (bupropion).
NASACORT (1991)/AZMACORT (1984) (triamcinolone)

It has always been the practice of CDER to allow multiple trademarks of the same active ingredient for different approved indications where the different indications are marketed as different products by different companies. CDER has no objection to generic manufacturers adopting trademarks for ANDAs that are different from the innovator trademark.

But at the annual Food, Drug and Law Institute (FDLI) annual meeting on April 19, 2001, OPDRA announced a change in policy, namely, that at least in the opinion of some at FDA there are too many "unnecessary" trademarks and the agency was "raising the bar when it came to trademarks in the interest of safety". At this meeting, OPDRA publicly announced that CDER would "strongly discourage" multiple trademarks for the same company for the same active ingredient. OPDRA has announced that a draft Guidance and MaPP are being developed and will be published for comment on or about April 2002. These will include language that will "strongly discourage" the use of multiple trademarks. OPDRA has acknowledged that the practice of allowing the adoption of different trademarks for the same active ingredient by different companies will continue.

Based on various comments from CDER, CDER's change in policy appears to be based on the following reasoning and concerns. More products means more mix ups; more product names aggravates the problem; unnecessary names should be eliminated or reduced; adoption of different trademarks by different companies, respectively, for the same active ingredient is acceptable; adoption of more than one trademark by the same company for the same active ingredient is unnecessary and unduly proliferates trademarks, raising the probability of product mix ups, double-dosing, and confusion among health care providers.

The PTS believes that CDER has signaled an intention to end to its practice of giving reasonable consideration to the adoption of a second trademark for the same active ingredient by the same company, which characterized past decisions regarding the use of multiple trademarks, and is moving to establish an ambiguous, onerous standard that is tantamount to an outright prohibition against multiple trademarks.

PTS Position - Multiple Trademarks Provide Patient Benefits

PTS believes that trademarks by their nature are distinctive. Trademarks are carefully selected and checked for likelihood of confusion. Trademarks provide an effective communication channel with the relevant public, helping to inform patients and health care providers who can make better choices. Adoption of multiple trademarks done properly will avoid confusion, double-dosing, etc.

One of the fundamental goals of clinical research for marketed products is to find additional benefits for patients. This can call for research into different indications, different dosage forms, different dosage concentrations, different dosage levels, different dosage regimens and different information for the health professionals and patients. When the sum total of all or some of these differences reaches a critical mass, it is often in the patient's best interest to create a distinctive identity for the product with the help of different packaging, different trade dress, and different information to support the new therapeutic use in an optimal manner. Perhaps the most necessary component of that new identity is a different trademark.

There are times when a strong brand identity is created for a first marketed drug product for an active ingredient in a therapeutic area that carries a social stigma. Use of the drug product in a new beneficial clinical setting could be compromised if the social stigma attached to the trademark is strong enough to discourage the patient from accepting and using the product. Among the powerful social stigmas associated with existing products are:

AIDS
HIV
Mental disease
Sexually transmitted disease
Cancer
Street drug reputation
Sexual dysfunction
Urinary dysfunction

Apart from social stigma issues, denial of multiple trademarks can increase the risk of medication errors and compromise patient safety. For example, if a new indication has a different dose concentration, a different injectable route of administration, and a different regimen, use of the familiar trademark in a new clinical context could create a hazardous situation for the patient. The PTS holds the view that CDER must consider both the risks associated with dangerous differences in doses and indications under a single trademark, and the benefit associated with a distinctly different trademark developed to help practitioners and patients take optimal advantage of new indications.

Aside from patient safety issues, a distinct trademark for a new indication has significant value in communicating relevant information to practitioners and patients. The ZYBAN (bupropion) experience is that public health interests are being served through a major communication effort to encourage people to stop smoking. The smoking-related material that is part of the labeling for ZYBAN (bupropion) makes a significant contribution to the product's success in curbing or eliminating the smoking dangers in patients who follow the program.

Products with multiple indications and a single trademark can create communication problems between practitioners and patients. For example, a product with one trademark and multiple indications, such as epilepsy, bi-polar disease, and migraine headache, could create confusion among patients when someone being treated for bi-polar disease interacts with a patient being treated for epilepsy. There is a risk that one of the patients could assume the doctor is withholding information about a problem.

The PTS is not aware of any data that shows past approvals of multiple trademarks have created any medication errors that resulted in patient harm.

Inconsistency of CDER Position on Multiple Trademarks

1. **Position on Innovator Company and NCE Products.** It appears that CDER's interest in trademark restriction is limited to innovator companies that have clinical data to support multiple indications and/or formulations and who wish to market the same active ingredient under different trademarks to highlight such differences.

2. **Position on Trademarks for Owners Of Off Patent Products (ANDA Holders).** There does not seem to be a comparable restriction on ANDA holders who place new trademarks on off-patent active ingredients.

3. **Position on Trademarks from Distributors of Off Patent Products.** Currently there is a gap in regulations that permit distributors of off-patent products to come to market with a trademark that has not been reviewed by CDER. This has the potential to disrupt the orderly review of trademarks that move through both the PTO and CDER processes. The MaPP and Guidance are expected to close this regulatory gap.

4. **Position on Trademarks for new NDAs Licensed to a Third Party.** Currently there is every indication that CDER would allow the same active ingredient to be marketed under different trademarks for different NDAs (and different indications) where the NDAs are not owned by the same entity.

Safety of Multiple Trademarks

Trademarks created and selected through a process like the one described in this paper are by and large quite distinctive and safe to use. Trademarks serve multiple valuable purposes and are in the public interest as well as benefiting the owner. Prior experience demonstrates that multiple trademarks adopted by the same company for the same drug can co-exist safely. There are no substantial data to suggest otherwise. Separate companies, including generics, are permitted to adopt trademarks for ANDAs that are different from the innovator trademark. A prohibition against adoption of multiple trademarks by the same company is not reasonable, does not further CDER's interest, and is counterproductive, illegal and discriminatory. The prior practice should be restored immediately.

LEGAL ANALYSIS

Trademarks Are Protected Commercial Speech Under the First Amendment

By communicating information to consumers about the type and quality of a given product, a trademark inherently proposes a transaction and, therefore, is typically treated as an act of constitutionally protected commercial speech. See Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 762 (1976) ("propos[al] of a commercial transaction" is test for commercial speech); see also Friedman v. Rogers, 440 U.S. 1, 11 (1979) (a trade name, which generally receives the same protection under the law as trademarks, "is used as part of a proposal of a commercial transaction" and is protected commercial speech under First Amendment); 5 McCarthy on Trademarks and Unfair Competition § 30:139, at 31-221 (4th ed. 2001) ("[A] firm's trademark is the most important element of commercial speech which is communicated to customers."). To be valid, agency action limiting such commercial speech must meet the test set forth in Central Hudson Gas & Electric Corp v. Public Service Commission, 447 U.S. 557, 566 (1980).

Under *Central Hudson*, the initial inquiry is whether the speech at issue concerns lawful activity and is not misleading. See id. The First Amendment generally protects commercial speech because the speech "assists consumers and furthers the societal interest in the fullest possible dissemination of information." Id. at 563. Regulations that effectively ban truthful, nonmisleading commercial speech about a lawful product typically "hinder consumer choice [and] impede debate over central issues of public policy" and, therefore, "rarely survive constitutional review." 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503, 504 (1996). On the other hand, speech that is either inherently misleading or related to illegal activity is generally not protected because it does not serve a public purpose. See *Virginia State Bd. of Pharmacy*, 425 U.S. at 771 ("Untruthful speech, commercial or otherwise, has never been protected for its own sake."); Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376, 388 (1973) (denying constitutional protection to speech about illegal activity).

The trademarks implicated by the proposed FDA action clearly would satisfy the threshold inquiry in *Central Hudson*. As noted above, by differentiating among products and competitors, trademarks generally serve an important role in informing consumers, not in misleading them. The concern, instead, is the situation where two different drugs are marketed under confusingly similar sounding or appearing names, but even errors in these situations compose only a small fraction of overall medication errors and are exceedingly rare when compared to the total number of prescriptions filled annually. The case law makes clear: "[t]he FDA may not restrict speech based [simply] on its perception that the speech could, may, or might mislead." Washington Legal Found. v. Henney, 56 F. Supp. 2d 81, 85 (D.D.C. 1999).[3] Rather, for the FDA's ban on multiple trademarks to survive constitutional scrutiny, it must have concrete proof that the trademarks at issue are inherently misleading.

In the absence of any such evidence, *Central Hudson* dictates that the proposed FDA action must satisfy three additional factors. Specifically, the action must (1) seek to supplement a substantial governmental interest; (2) directly advance that interest; and (3) be no more extensive than necessary to achieve the given objective. *Central Hudson*, 447 U.S. at 566; see also Bd. of Trustees of the State

[3] See footnote 5 below for citations to the prior and subsequent decisions in this litigation.

University of New York v. Fox, 492 U.S. 469, 480 (1989) (interpreting final factor to mean that restriction must be "narrowly tailored to achieve the desired objective").

Because the government undeniably has an interest in protecting the health and safety of its citizens, see Posadas de Puerto Rico Assoc. v. Tourism Co. of Puerto Rico, 478 U.S. 328, 341 (1986), the constitutionality of the proposed FDA action turns, first, on whether it directly advances that interest. On this point, the government "bears the burden of showing not merely that its [action] will advance its interest, but also that it will do so to a material degree." *44 Liquormart, Inc.*, 517 U.S. at 505 (internal quotation and citation omitted). To meet this burden, "mere speculation or conjecture" is insufficient; instead, the FDA again must offer concrete proof that "the harms it recites are real and that its restriction will in fact [substantially] alleviate them." Edenfield v. Fane, 507 U.S. 761, 770-71 (1993).

There is little doubt that the FDA's proposed action would fail the penultimate prong of the *Central Hudson* test. Again, there is no evidence that any more lives would be saved by diminishing or eliminating a sponsor's use of multiple trademarks for a given drug. First, such action would not address poor handwriting on prescriptions, distraction in the pharmacy, and other factors that contribute more significantly to medication errors. Second, any decrease in the likelihood of medication errors in isolated instances where two product names are similar is outweighed by the increase in the risk of medication error resulting from contra-indicated use, incorrect dosage concentrations and regimens, and patient confusion. Third, and perhaps most importantly, such action may lead to patients who, out of fear of the social stigma that is attached to the trademark, refuse treatment for their ailments. At best, then, the FDA's proposed action would provide "only ineffective or remote support for the government's purpose," in which case it "may not be sustained." *Central Hudson*, 447 U.S. at 564.

Yet, even if restricting the use of multiple trademarks were deemed to advance the FDA's interest in preserving public health and safety, the restriction would still run afoul of the First Amendment because it is not narrowly tailored to achieve the FDA's objective. To satisfy the final element of *Central Hudson*, there must be a "reasonable fit" between the agency action that abridges speech and the government's legitimate goals. *Bd. of Trustees of the State University of New York*, 492 U.S. at 480. Further, the Supreme Court has made clear that federal agencies should not effectively destroy business assets, including intellectual property, "if less drastic means will accomplish the same result." Jacob Siegel Co. v. FTC, 327 U.S. 608, 613 (1946) (internal quotations and citation omitted).[4]

[4] For example, in FTC v. Royal Milling Co., 288 U.S. 212 (1932), respondents used the word "milling" in their trade names, although they did not themselves grind the wheat they sold. While the Court agreed that the names were misleading, it held that full excision of the names was too extreme a remedial measure:

> These names have been long in use . . . . They constitute valuable business assets in the nature of good will, the destruction of which probably would be highly injurious and should not be ordered if less drastic means will accomplish the same result. The orders should go no further than is reasonably necessary to correct the evil and preserve the rights of competitors and public; and this can be done, in the respect under consideration, by requiring proper qualifying words to be used in immediate connection with the names.

Id. at 217.

Negating the ability of sponsors to use multiple trademarks for a particular drug is precisely the type of drastic action against which the Supreme Court has warned. First, as noted, it is not clear at all that the action would achieve the government's purpose of reducing medication errors. Second, there are alternative, less restrictive means of addressing the problem of medication errors – such as addressing the problem of poor handwriting, distraction in the pharmacy and reviewing multiple trademarks on the same basis upon which it reviews all other trademarks – that are almost certainly more likely to achieve the government's goal. Accordingly, the FDA's action, rather than being a reasonable fit with its stated goal of decreasing medication errors, is significantly more extensive than reasonably necessary and, therefore, would be struck down under *Central Hudson*.

Finally, it bears mention that the FDA may not restrict a sponsor's right to commercial speech, including the use of multiple trademarks, merely because regulation of the sponsor is within the agency's regulatory power. Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 60 (D.D.C. 1998).[5] The Supreme Court clearly has rejected the proposition that, because the government

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[5] The *Washington Legal Foundation* cases cited in this section provide the most recent illustration of the applicability of *Central Hudson* to FDA action. In the first case, Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 72-73 (D.D.C. 1998) (*WLF I*), the court found that, under *Central Hudson*, FDA Guidance Documents infringed upon the right of pharmaceutical manufacturers to disseminate information relating to off-label uses because the Guidance Documents were more extensive than necessary to advance the legitimate governmental interest in public health and safety. A government motion to limit the scope of the injunction issued in *WLF I* was rejected, though it led the court to order additional briefing on the constitutionality of the Food and Drug Administration Modernization Act (FDAMA), which contained provisions that superseded the Guidance Documents at issue in the first case. See Washington Legal Found. v. Friedman, 36 F. Supp. 2d 16, 18 (D.D.C. 1999) (*WLF II*). After receiving the supplemental briefing, the district court concluded the FDAMA "largely perpetuates the polices held unconstitutional [in *WLF I*] and therefore may not be applied or enforced by FDA." Washington Legal Found. v. Henney, 56 F. Supp. 2d 81, 84 (D.D.C. 1999) (*WLF III*).

On appeal, however, the government clarified its position that the FDAMA and the Guidance Documents simply provided a "safe harbor" which outlined certain forms of conduct that were lawful. See Washington Legal Found. v. Henney, 202 F.3d 331, 335 (D.C. Cir. 2000) (*WLF IV*). The FDA further stipulated that neither the FDAMA nor the Guidance Documents "independently authorize[d] [it] to prohibit or to sanction speech." Id. As a result, the appellate court noted that there was no longer a constitutional question in dispute and vacated the core holdings of the district court in *WLF I* and *WLF III*. Id. at 336-37; see also Washington Legal Foundation v. Henney, 128 F. Supp. 2d 11 (D.D.C. 2000) (*WLF V*) (district court's previous injunction was in fact based entirely on constitutional law and, therefore, was wholly vacated by the appellate decision).

Nevertheless, the appellate court stated that, in issuing its ruling, it did not intend to "criticize the reasoning or the conclusions of the district court. As we have made clear, we do not reach the merits of the district court's First Amendment holdings." *WLF IV*, 202 F.3d at 337 n.7. Accordingly, the district court's discussion in *WLF I* and *WLF III* of the FDA's ability to restrict constitutionally protected commercial speech still may provide useful guidance – after all, as the FDA recently

possesses power in one area, it is permitted to restrict speech in that area. *44 Liquormart, Inc.*, 517 U.S. at 512 ("[S]peech restrictions cannot be treated as simply another means that the government may use to achieve its ends."). Rather, if commercial speech is involved, a government agency must satisfy all parts of the *Central Hudson* test. As illustrated above, the FDA's proposed action falls far short of meeting this constitutional requirement.

Denying the Right to Use Multiple Trademarks Is Inconsistent With a Manufacturer's Fifth Amendment Property Rights

In addition to unconstitutionally restricting commercial speech, the elimination of multiple trademarks would constitute an impermissible taking of the sponsors' property without just compensation in violation of the Fifth Amendment. Trademarks possess all the fundamental attributes of property: They may be the subject of a trust; they can pass to a trustee in bankruptcy; and, as long as they include the goodwill of the business or product, they may be assigned. The greater the demand to use the trademark, the greater the value that will accrue to the assignment and the greater the harm caused by infringement. Sponsor investment in global trademarks is often significant. At present, the typical creative development costs for a global trademark is in the $150,000 range. Costs for legal clearance and global registrations are often an additional $150,000. If FDA prohibits the adoption of a trademark late in the NDA approval process the existence of a global brand is placed in significant jeopardy. When companies elect to communicate information about the trademark in the pre-launch phase, the awareness of the name among target physicians can have brand equity in the millions of dollars. Therefore, the law grants the trademark owner the right to injunctive relief against a private party's infringing action, such as the use of a confusingly similar mark. See 15 U.S.C. § 1116. More important for present purposes, when the government is the infringing party, the Fifth Amendment affords protection to trademark owners. See Maltina Corp. v. Cawy Bottling Co., 462 F.2d 1021, 1027 (5th Cir. 1972) (trademarks are treated as property under the laws and policy of the United States, including the Constitution); see also Ruckelhaus v. Monsanto, 467 U.S. 986, 1003-04 (1984) (trade secret property "is protected by the Takings Clause of the Fifth Amendment").

The case law makes clear that the FDA's actions would constitute a public "taking." Because the FDA proposes to deprive companies of their trademark rights, its action would be analogous to cases in which the government physically intrudes upon private property. These cases almost uniformly have been considered public takings. That the property at issue is intangible should not affect the conclusion that there has been a taking. See *Ruckelhaus*, 467 U.S. at 1003 ("That intangible property rights . . . are deserving of the protection of the Takings Clause has long been implicit in the thinking of this court."). The FDA action would deprive the property of economic value, thereby grossly infringing upon the reasonable expectation held by the sponsor at the time of investment. See id. at 1005 (citing PruneYard Shopping Center v. Robins, 447 U.S. 74, 83 (1980)). Such an action, without compensation, "would violate the bedrock principles . . . embodied in the Fifth Amendment." *Maltina Corp.*, 462 F.2d at 1027. In addition, the speculative nature of the FDA's prohibition as shown above and the denial of patient benefits that would result from the multiple trademark restriction is unreasonable and arbitrary and would be in violation of the protection of the due process clause of the Fifth Amendment.

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acknowledged in response to a citizen petition from WLF, "in . . . furthering the Agency's mission to protect the public health, [FDA] must respect the rights guaranteed by the First Amendment." *FDA Letter to Washington Legal Foundation*, 28 January 2002, p. 1.

Mindful of these principles, President Reagan in 1988 issued Executive Order 12,360, entitled "Governmental Actions and Interference with Constitutionally Protected Property Rights," which sets forth certain criteria and guidelines to be followed by agencies so that their actions do not result in unnecessary takings. Exec. Order. No. 12,360, 3 C.F.R. 554 (1988). According to the Order, an agency restriction upon property rights "shall not be disproportionate to the extent to which the use [of the property] contributes to the overall problem the restriction is imposed to redress." Id. at § 4(b). Further, "the mere assertion of a public health and safety purpose is insufficient to avoid a taking," id. at § 3(c), which according to Attorney General Guidelines implementing the Order, occurs when governmental action "[has] an effect on private property sufficiently severe as to effectively deny economically viable use." Attorney General's Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings § IV(B) (1988) (unpublished). The Order further cautioned that agency action for the protection of public health and safety "should be undertaken only in response to real and substantial threats to public health and safety, be designed to advance significantly the health and safety purpose, and be no greater than necessary to achieve the health and safety purpose." Exec. Order. No. 12,360, § 3(c).

It is clear, then, that the Executive Branch itself would recognize the CDER action as an impermissible taking that should not be pursued. As the First Amendment discussion above reveals, the arbitrary elimination of multiple trademarks would be an extreme response to the problem of medication errors and could conceivably harm, rather than enhance, public health and safety.

CDER Action Eliminating the Use of Multiple Trademarks Would Be Arbitrary and Capricious Under the Administrative Procedure Act

CDER's proposed action would contravene the Administrative Procedure Act ("APA") as well. The APA provides that agency actions may be set aside if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(A)(2). To ensure an action does not rise to this level, an agency must show a "rational connection between the facts found and the choice made." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co. 463 U.S. 29, 43 (1983) (internal quotations and citation omitted).

CDER's articulated reason for restricting the rights of trademark holders – a belief that it would reduce the risk of medication errors – is not adequately supported by any agency findings. To the contrary, CDER does not appear to have considered the real possibility that the use of multiple trademarks actually helps prevent medication errors. In these circumstances, the attempt to circumvent the constitutional and statutory rights of the trademark owner would be arbitrary and capricious.

CDER's Considered Action is Contrary to Statutory Presumption of the Right to Use Registered Trademarks

The proposed CDER action would also be inconsistent with the unequivocal provisions of the federal trademark laws and the express intent of Congress in enacting them. Under the Lanham Trademark Act of 1946, the registration of a trademark on the principal register of the Patent and Trademark Office (PTO) creates a presumption of the registrant's ownership and exclusive right to use the trademark "in commerce on or in connection with the goods specified in the registration." 15 U.S.C. §§ 1057(b), 1115(a). Congress enacted this statutory presumption, and the Lanham Act more broadly,

to afford the greatest protection possible to trademarks and thereby minimize the use of deceptive and misleading marks in commerce. See 15 U.S.C. § 1127.

By arbitrarily precluding valid trademarks from commerce, CDER's proposed action could undermine this statutory framework and weaken the trademark system for pharmaceutical products. Because the process for obtaining official registration of a trademark is thorough and "gives appropriate effect to [the] expertise" of the PTO, Tigrett Industries, Inc. v. Top Value Enterprises, Inc., 217 F. Supp. 313, 316 (W.D. Tenn. 1963), any FDA policy that would eliminate or restrict the use of multiple trademarks would constitute an impermissible attempt to abrogate the registration provisions of the Lanham Act. See 1 Norman J. Singer, Statutes and Statutory Construction § 3.06, at 55 (5th ed. 1994) ("[A]dministrative agencies are [not] empowered to rewrite statutes to suit their notions of sound public policy when the legislature has clearly and unambiguously spoken."); see also New York v. United States, 505 U.S. 144, 182 (1992) ("The Constitution's division of power among the three branches is violated where one branch invades the territory of another.") In doing so, the FDA, contrary to well-settled legal principles, would effectively nullify the statutory presumption of a registrant's right to use its trademark.

A Restriction Upon a Pharmaceutical Company's Right to Hold Multiple Trademarks Would Be Contrary to Article 20 of TRIPS

In addition to infringing upon constitutional and statutory provisions, FDA's position on multiple trademarks would be inconsistent with the international obligations of the United States under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 20 of TRIPS states:

> The use of a trademark in the course of trade shall not be *unjustifiably encumbered* by special requirement, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings.[6] (emphasis added)

This language embodies a larger principle that the actions of signatory nations should not restrict the use of a mark, domestic or foreign, unless absolutely necessary.

The elimination of a trademark or a class of trademarks is the ultimate encumbrance, and, in the case of FDA's proposed action, is not justifiable. There is no indication that the elimination of a sponsor's right to use multiple marks for a given drug would improve the medication's safety. Nor would the elimination of multiple marks alter consumers' reasonable expectations about the safety of the trademarked drug. Indeed, consumer expectations, which often are dispositive in determining whether a particular action is justified, are more likely to be confused by the CDER action. The CDER action, therefore, could subject the United States to a challenge before the World Trade Organization.

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[6] The language that a trademark shall not be "unjustifiably encumbered" was originally proposed by the United States. See Annette Kur, *TRIPs and Trademark Law*, *in* From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights 111 (Friedrick-Karl Beier and Gerhard Schricker eds., 1996). This language was a response to the propensity of developing countries to place restrictions on the use of foreign trademarks.

CDER Proliferation Concern

The CDER concerns about a proliferation of trademarks has no legal basis. There are no numerical limits on trademarks in any of the laws governing FDA, trademarks, or the industry.

SUMMARY AND RELIEF REQUESTED

The current CDER restriction on multiple trademarks and its proposed inclusion in a soon-to-be published Guidance and MaPP are excessive and inappropriate actions to address the agency's concern about medication errors. There is no evidence that medication errors result solely or even predominantly from multiple trademarks for the same active ingredient. Such an arbitrary restriction violates the First Amendment and the Fifth Amendment, is arbitrary and capricious under the Administrative Procedure Act, is contrary to the statutory presumption of the right to use registered trademarks, and violates Article 20 of TRIPS. The agency should continue its past practice of reviewing requests for multiple trademarks on the same basis upon which it reviews and approves all other trademarks.

Respectfully submitted,

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